IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXALTA INCORPORATED, a Delaware corporation; and BAXALTA GMBH, a Swiss company, Plaintiffs, v. GENENTECH, INC., a Delaware corporation; and CHUGAI PHARMACEUTICAL CO., LTD., a Japanese company, Defendants.	C.A. No. _____ JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT AND
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Baxalta Incorporated and Baxalta GmbH (collectively, "Baxalta"), by its attorneys, alleges as follows for its Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement against Genentech, Inc. ("Genentech") and Chugai Pharmaceutical Co., Ltd. ("Chugai") (collectively, "Defendants"):

NATURE OF THE ACTION

1. This is an action for patent infringement and for a declaratory judgment of patent infringement of United States Patent No. 7,033,590. This action arises out of Defendants' current and/or imminent manufacture, use, sale, offer to sell within the United States, and/or importation into the United States of Defendants' humanized bispecific antibody that binds Factor IX/IXa and Factor X to treat hemophilia A. Defendants developed this antibody under the name "emicizumab." Emicizumab is also known as ACE910.

PARTIES

2. Plaintiff Baxalta Incorporated, a wholly owned subsidiary of Shire plc ("Shire"), is a corporation organized under the laws of Delaware with its principal place of business at 1200 Lakeside Drive, Bannockburn, Illinois.

3. Plaintiff Baxalta GmbH, a subsidiary of Baxalta Incorporated, is a Swiss company with its place of business in Glattpark (Opfikon), Switzerland.

4. Shire, including its Baxalta subsidiaries, is the global biopharmaceutical leader in developing, manufacturing, and commercializing transformative therapies to treat orphan and underserved disease conditions in hematology, immunology, and oncology.

5. Upon information and belief, Genentech is a corporation organized under the laws of Delaware with its principal place of business at 1 DNA Way, San Francisco, California 94080. Upon information and belief, Genentech is a wholly owned subsidiary of Roche Holdings, Inc. Upon information and belief, Roche Holdings, Inc. is a subsidiary of Roche Holding AG, which is a Swiss company with its principal place of business in Basel, Switzerland.

6. Upon information and belief, Chugai is a company organized under the laws of Japan with its principal place of business in Tokyo, Japan. Upon information and belief, Chugai is also a subsidiary of Roche Holding AG. Roche Holdings, Inc. and Roche Holding AG will be collectively referred to herein as "Roche."

JURISDICTION AND VENUE

7. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 et seq.

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over the Defendants at least by virtue of the fact that they conduct business in Delaware, have availed themselves of the rights and benefits under Delaware law, and/or have engaged in substantial and continuous contacts in Delaware.

10. Upon information and belief, Chugai is in the business of developing, manufacturing, formulating, marketing, and selling pharmaceutical products, including antibody products. Upon information and belief, Chugai developed emicizumab.

11. Upon information and belief, Chugai has already exported or imminently intends to export emicizumab into the United States for marketing and commercial use and sale throughout the United States and in this District.

12. Upon information and belief, Genentech is organized in Delaware.

13. Upon information and belief, Genentech is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug and biologic products, including antibody products. Upon information and belief, Genentech, directly or indirectly, currently markets and sells pharmaceutical drug and biologic products throughout the United States and in this District.

14. Upon information and belief, Genentech, directly or indirectly, has already imported and used or imminently intends to import and use emicizumab in the United States for marketing and commercial use and sale throughout the United States and in this District.

15. Venue is proper in this District and before this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

THE PATENT-IN-SUIT

16. On April 25, 2006, United States Patent No. 7,033,590 (the "'590 Patent"), entitled "Factor IX/Factor IXa Activating Antibodies and Antibody Derivatives," issued to Baxter Aktiengesellschaft as assignee of the named inventors Friedrich Scheiflinger, Randolf Kershbaumer, Falko-Guenter Falkner, Friedrich Dorner, and Hans-Peter Schwarz. A copy of the '590 Patent is attached as Exhibit A.

17. In March 2016, the '590 Patent was assigned to Baxalta Incorporated and Baxalta GmbH. The '590 Patent is fully maintained and is valid and enforceable.

HEMOPHILIA BACKGROUND AND THE INFRINGING PRODUCT

A. BACKGROUND FOR HEMOPHILIA A TREATMENTS

18. The human body possesses a complex mechanism to stop bleeding or cause hemostasis. This mechanism involves the interaction of platelets to form a primary platelet plug and the interaction of blood coagulation factors to coagulate or clot the blood to stabilize the platelet plug. The combined activity of the platelets and the blood coagulation factors stops bleeding. First, platelets circulating in the blood stream will adhere to an injured area, such as a blood vessel. Once attached to an injured area, the platelets are activated and form a platelet plug. Second, blood coagulation factors initiate a blood coagulation cascade to begin creating a clot. A clot is formed by the blood coagulation factors' formation of a protein called fibrin. Fibrin mesh is produced over and around the platelet plug, which helps hold the plug in place and creates a stable platelet plug.

19. Fibrin is generated by a cascade process that involves the successive reaction of different blood coagulation factors in the body. These blood coagulation factors are named by Roman numerals, e.g., "Factor I," "Factor II," and so on. Part of the blood coagulation cascade involves activated Factor VIII ("Factor VIIIa") and activated Factor IX ("Factor IXa"), which

form a complex that converts Factor X to Factor Xa. Factor Xa activates Factor II (prothrombin), converting Factor II to Factor IIa (thrombin). Factor IIa cleaves Factor I (fibrinogen), converting it into fibrin, which ultimately stops bleeding by forming a fibrin clot over a platelet plug.

20. Hemophilia patients lack or have an insufficient amount of specific blood coagulation factors, making it difficult or impossible to form a stable platelet plug and thus stop bleeding. Patients who lack or are deficient in Factor VIII suffer from hemophilia A.

21. Hemophilia A patients' lack or insufficiency of Factor VIII makes it difficult or impossible to form the complex necessary for activated Factor IXa to convert Factor X to Factor Xa, reducing or precluding the subsequent reactions that lead to the formation of fibrin. In turn, this leads to an inability or diminished ability to form a platelet plug to stop bleeding in patients that have hemophilia A.

22. Shire, along with its Baxalta subsidiaries, is the world's leading provider of products used in the treatment of hemophilia. Shire's products include the market-leading drug ADVATE as well as ADYNOVATE, OBIZUR, RECOMBINATE, RIXUBIS, and HEMOFIL M.

B. DEFENDANTS' INFRINGING PRODUCT

23. Upon information and belief, Defendants' product emicizumab is an antibody that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa as claimed in Baxalta's '590 Patent.

24. Upon information and belief, since at least May 2014, Chugai actively researched and developed emicizumab, including the development and approval of clinical trials.

25. Upon information and belief, since at least September 2015, Genentech also has collaborated with Chugai on the research and development of antibody product candidates, including emicizumab, for commercial use and sale in the United States.

26. In September 2015, Genentech announced that the FDA granted breakthrough therapy designation to emicizumab "for the prophylactic treatment of people who are 12 years or older with hemophilia A with factor VIII inhibitors." Ex. B, Genentech Breakthrough Status Press Release at 1. Genentech explained that the breakthrough therapy designation is "designed to accelerate the development and review of medicines that demonstrate early clinical evidence of a substantial improvement over current treatment options for serious diseases." *Id.*

27. On December 22, 2016, Roche announced that the Phase III clinical trials for emicizumab necessary to submit its Biologics License Application ("BLA") to the FDA had been completed. Ex. C, Roche Dec. 22, 2016 Press Release. A BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. *See* 21 CFR § 601.2.

28. Upon information and belief and publicly available media reports, Defendants expect to launch emicizumab in the United States in the fourth quarter of 2017. Ex. E, Roche Pipeline Report at 1448; Ex. F, Michael Varney Presentation at 5; Ex. G, Roche First Quarter 2017 Investor Call Presentation at 29.

29. According to standard industry practice, the FDA typically takes at most about six months to complete its review of a BLA for a product that has received breakthrough therapy designation. Thus, a launch in the United States in the fourth quarter of 2017 would require Defendants to file a BLA for emicizumab between April and June of 2017 to meet their 2017 launch target. During Roche's First Quarter 2017 Investor Call, Roche announced that the

planned regulatory filings for ACE910 were on track and would be completed by the middle of 2017.[1] Roche further announced that certain portions of the BLA for ACE910, namely the Chemistry, Manufacturing, and Controls section, would be filed on a rolling basis. *See id.* Thus, upon information and belief, the filing of Defendants' BLA for emicizumab with the FDA to obtain licensure is either ongoing or imminent.

30. Upon information and belief and as previously alleged in Baxalta's complaint filed on April 8, 2016 in connection with a litigation proceeding in Japan, under standard industry practice, Defendants would typically begin manufacturing and/or importing emicizumab for commercial sale at least one year in advance of an anticipated launch date, *i.e.*, in or around November 2016. Thus, upon information and belief, Defendants' use, manufacture, and/or importation of emicizumab has already begun or is imminent.

31. Upon information and belief, FDA approval of emicizumab would permit Defendants to immediately offer to sell and sell the drug within the United States.

32. For example, Defendant Chugai's 2016 Annual Report stated the following:

> We plan to file applications in and outside Japan for regulatory approval of emicizumab as a potential treatment for hemophilia A. Aiming for the speediest possible launch, we have started to set up of [sic] the production system for emicizumab and have begun construction of a biologic API production facility at the Ukima Plant to meet expanding global demand.

Ex. H, Chugai Annual Report 2016 at 32.

33. Upon information and belief, Genentech has hired and continues to grow its sales force to promote the marketing and sale of emicizumab in the United States. Upon information and belief, Genentech has been actively hiring a sales force of Hemophilia Clinical Specialists. For example, Genentech posted numerous job postings for sales position in its Hemophilia group in February and March of 2017. Ex. I, March 14, 2017 job postings.

[1] http://78449.themediaframe.com/dataconf/productusers/roche/mediaframe/18813/indexr.html

34. Upon information and belief, Defendants intend to market emicizumab in the United States under the brand name "HEMLIBRA," "HEMLEKA," or "SEITMA." On June 4, 2015, Chugai filed with the U.S. Patent and Trademark Office ("USPTO") applications for its intent to use the mark "HEMLIBRA" and "HEMLEKA" in commerce in connection with "pharmaceutical preparations for the treatment of Hemophilia A." "HEMLIBRA" and "HEMLEKA" were successfully registered on January 26, 2016. *See* Ex. J, HEMLIBRA, Reg. No. 4,892,349; Ex. K, HEMLEKA, Reg. No. 4,892,348. On September 30, 2015, Chugai filed with the USPTO an application for its intent to use the mark "SEITMA" in commerce in connection with "pharmaceutical preparations for the treatment of Hemophilia A." "SEITMA" was successfully registered on May 17, 2016. *See* Ex. L, SEITMA, Reg. No. 4,960,184.

35. In sum, on information and belief, Defendants are either currently using, manufacturing, and/or importing emicizumab for commercial sale in the United States, including for sale in this District, or plan to do so imminently. Upon information and belief, Defendants have already or imminently plan to submit a BLA for emicizumab to the FDA seeking approval to sell emicizumab in the United States. Upon information and belief, Defendants plan to sell and offer for sale emicizumab immediately upon the FDA's approval for their BLA, which is expected in the fourth quarter of 2017.

36. Defendants' infringing acts as described herein will immediately and irreparably harm Baxalta.

FIRST CAUSE OF ACTION
(Infringement of the '590 Patent)

37. Baxalta realleges and incorporates by reference the allegations contained in paragraphs 1-36.

38. On information and belief, Defendants have infringed the '590 Patent by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of emicizumab before the expiration of the '590 Patent and by actively inducing and/or contributing to the infringement of others in violation of 35 U.S.C. § 271(a), (b), (c), or (g).

39. Emicizumab and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claims 1, 4, 15, 17, and 19 of the '590 Patent. *See e.g.* Ex. M, Claim Chart.

40. Baxalta will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '590 Patent.

41. Baxalta has no adequate remedy at law.

42. This case is exceptional, and Baxalta is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SECOND CAUSE OF ACTION
(Declaratory Judgment of Infringement of the '590 Patent)

43. Baxalta realleges and incorporates by reference the allegations contained in paragraphs 1-42.

44. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. §§ 100 et seq., including 35 U.S.C. § 271(a), (b), (c), or (g), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

45. There is an actual case or controversy such that the Court may entertain Baxalta's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

46. On information and belief, Defendants' imminent submission of a BLA to the FDA seeking approval to market emicizumab in the United States on an expedited basis, coupled

with Defendants' commercial activities in support of its importation and launch of emicizumab for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Defendants will directly infringe, or actively induce and/or contribute to infringement of, valid and enforceable claims of the '590 Patent before its expiration in violation of 35 U.S.C. § 271(a), (b), (c), or (g).

47. Emicizumab and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claims 1, 4, 15, 17, and 19 of the '590 Patent. *See* Ex. M, Claim Charts.

48. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

49. Baxalta will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '590 Patent.

50. Baxalta has no adequate remedy at law.

51. This case is exceptional, and Baxalta is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Baxalta prays for judgment against Defendants Genentech, Inc. and Chugai Pharmaceutical Co., Ltd., and respectfully requests the following relief:

1. A judgment that the '590 Patent has been infringed and will be infringed by Defendants;

2. A judgment for an injunction enjoining each Defendant, and its officers, agents, servants, and employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling emicizumab within the

United States, or importing emicizumab into the United States, prior to the expiration of the '590 Patent pursuant to 35 U.S.C. § 283;

3. To the extent that Defendants have or will commercially manufacture, use, offer to sell, or sell emicizumab within the United States, or import emicizumab into the United States, prior to the expiration of the '590 Patent, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

4. A judgment that this is an exceptional case and that Plaintiff be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

5. Costs and expenses in this action; and

6. Such other and further relief as the Court deems just and appropriate.

JURY DEMAND

Baxalta hereby demands a jury trial on all issues appropriately triable by a jury.

Date: May 4, 2017

/s/ Colm F. Connolly

Colm F. Connolly (#3151)
MORGAN, LEWIS & BOCKIUS LLP
1007 North Orange Street, Suite 501
Wilmington, DE 19801
Telephone: (302) 574-3000
Facsimile: (302) 574-3001
cconnolly@morganlewis.com

Michael J. Abernathy
Christopher J. Betti
Amanda S. Williamson
Jennifer M. Dienes
Maria E. Doukas
MORGAN, LEWIS & BOCKIUS LLP
77 West Wacker Drive, Fifth Floor
Chicago, IL 60601
Telephone: (312) 324-1000
Facsimile: (312) 324-1001
mike.abernathy@morganlewis.com
christopher.betti@morganlewis.com
amanda.williamson@morganlewis.com
jennifer.dienes@morganlewis.com
maria.doukas@morganlewis.com

Jessica A. Stow
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
Telephone: (215) 963-5000
Facsimile: (215) 963-5001
jessica.stow@morganlewis.com